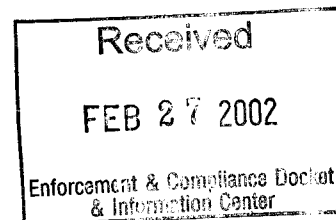


DOW CORNING

EC-2000-007
IV-D-111

February 27, 2002

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center (Mail Code 2201A)
Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue, NW
Washington, DC 20460



Dear Sir/Madam:

Dow Corning Corporation is pleased to submit comments on the Environmental Protection Agency's (EPA) proposed Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR) that was published in the 66 Federal Register 46162 (August 31, 2001).

Dow Corning Corporation (DCC) is a global company with approximately \$2.5 billion in annual sales, research and manufacturing facilities on five continents. DCC markets over 5,000 products to approximately 45,000 customers and has over 8,000 employees. Dow Corning's primary business is to develop, manufacture, and market silicones, related specialty chemical materials, and polycrystalline silicon. Dow Corning welcomes the efforts of the EPA to move in a direction that allows electronic reporting and record-keeping and understands the benefits that can be gained through this initiative. However, Dow Corning feels that the Proposed Rule, as written, will pose an undue financial and resource burden in addition to the cost of compliance with federal, state and local environmental regulations.

Dow Corning also supports the comments to the proposed rule that have been submitted by the Society of Quality Assurance and by the American Chemistry Council. In addition, the attached comments will focus on the potential financial and resource impact of CROMERRR on Dow Corning as a company that generates a wide range of electronic records and reports that would be subject to CROMERRR.

Please find attached a summary and discussion, based on our understanding of 40 CFR Parts 3, 51, *et al*, "Establishment of Electronic Reporting: Electronic Records; Proposed Rule."

Sincerely,

Handwritten signature of Kathleen P. Plotzke in black ink.

Kathleen P. Plotzke
Director, Health and Environmental
Sciences
Dow Corning Corporation
Health and Environmental Sciences

Handwritten signature of Joyce L. Henry in black ink.

Joyce L. Henry
Manager, Quality Assurance
Dow Corning Corporation
Health and Environmental Sciences

Handwritten signature of Mark J. Dabrowski in black ink.

Mark J. Dabrowski
System Manager
Dow Corning Corporation
Health and Environmental Sciences

Enclosure

SUMMARY

The EPA promulgated the proposed Cross-Media Electronic Reporting and Record-keeping Rule (CROMERRR) on August 31, 2001, to remove existing regulatory obstacles to electronic reporting and record-keeping across a broad spectrum of EPA programs. Allowing electronic reporting and record-keeping has the potential to improve efficiency in information management along with improved productivity of industry and government. While it is our belief that electronic reporting and record-keeping have the potential to improve quality and efficiency, we have concerns in the following areas:

1. Record retention requirements.
2. The complex submitter registration and re-registration.
3. Financial burden on the regulated.
4. The voluntary option of the proposed rule.
5. Lack of available technology with which to meet record retention requirements.

The proposed rule emphasizes electronic submission and record-keeping for environmental reports. However, the rule also impacts the chemical industries that submit reports supported by EPA TSCA/FIFRA Good Laboratory Practice Standards (GLP). As GLPs require meticulous data collection procedures along with extensive retention periods, the rule as proposed would add significant financial burden to the chemical industry.

As a result of these concerns, Dow Corning recommends that EPA reassess CROMERRR compliance costs to the TSCA/FIFRA regulated chemical industry and modify the rule prior to finalization.

DISCUSSION

1. Record retention requirements:

- ◆ EPA GLPs require retention of raw data and reports for the following time periods: a. For a period of at least ten years following the effective date of the applicable final test rule; b. For a period of at least ten years following the publication date of the acceptance of a negotiated test agreement; or c. in the case of any study used to support an application for a research or marketing permit approved by EPA, the period during which the sponsor holds any research or marketing permit to which the study is pertinent. The rate at which software and hardware are changing guarantees that systems will become obsolete which creates the need to maintain legacy systems or to migrate to new media every few years. Issues include the cost of migrating data and the cost of maintaining obsolete hardware or software to ensure functional capability. Maintaining old software is challenging and eventually all systems would need to be migrated. Migration involves extensive planning, Quality Control, and periodic review of the integrity of the electronic record to assure there has been no degradation. Accurate data migration is a time-consuming and expensive activity, especially with the maintenance of audit trails, metadata, and electronic signatures. We recommend that these costs associated with long-term archival of electronic records be evaluated prior to implementation of CROMERRR to more accurately determine the cost of the proposed rule.

2. Submitter registration and re-registration:

- ◆ The proposed rule appears to require significant resource and financial expenditures in order to meet the complex submitter registration and re-registration process.

- ◆ EPA estimates that for each facility, two employees will register with EPA to report electronically. We contend that the number of people who must register with EPA is greater than two per facility as there will generally be more than two people submitting information to allow us to be more flexible.
- ◆ The process of certifying signatures is very complex. The EPA proposes to require that an electronic document receiving system validate only electronic signatures that have been affixed after the submitter has scrolled through on-screen pages that present all the data to be certified in a human readable format. The volume of data submitted at any one time may be prohibitive in allowing for such on-line review.
- ◆ CROMERRR requires that the registrant periodically renew his or her electronic signature agreement. As the renewal process is written, it will cause undue burden on the regulated community. If nothing changes with the registrant then there is no apparent rationale to require renewal.

3. Financial burden:

- ◆ There is undue financial burden on the regulated community as a result of purchase and implementation of technology beyond current systems in order to attempt to comply with record-keeping controls.
- ◆ Most regulated facilities have numerous electronic record-keeping systems that generate, analyze, manage, or store data to meet EPA 40 CFR requirements.
- ◆ Given the number of such systems within a GLP facility, the costs will be substantial to upgrade or replace systems to assure compliance. Systems need to be compliant with electronic record requirements for audit trails, date and time-stamping, and archiving. Due to the existence of many validated "legacy" systems that are non-compliant with CROMERRR, a large amount of capital cost would be needed to bring all required systems up to an acceptable level of compliance. Either developing new software programs or purchasing new software or upgrades will result in significant validation and support costs. With the high number of systems in a GLP facility, these costs can be substantial.
- ◆ These capital costs are not one-time costs as technology changes rapidly and the cost of upgrades, which can be significant, must be factored into the overall financial burden.
- ◆ For each electronic data capture system, there would need to be gap and risk analyses, upgrades or replacements, and validation to ensure that CROMERRR requirements are met.
- ◆ It is unreasonable for the regulated community to believe that EPA will not require documentation (validation) that the system meets CROMERRR requirements for the electronic records. Such requirements include "secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator entries and actions that create, modify, or delete electronic records or documents."
- ◆ There also seems to be an assumption by EPA that there is a one-to-one relationship between an EPA program that has established reporting requirements under 40 CFR and the number of systems that a respondent maintains in order to capture the data that is reported. This is an enormous understatement.
- ◆ CROMERRR may also apply to other types of GLP records such as standard operating procedures, training records, master study schedule, and facility records.
- ◆ We urge EPA to re-evaluate the total costs of systems and labor hours based on the above items.
- ◆ As an example of the cost of this proposed rule, it would cost \$16,000 to upgrade a single Liquid Scintillation Counter to have e-record capabilities, and then take 80 + hours to test and validate the instrument to assure compliance.
- ◆ EPA has indicated that regulated entities may not maintain, nor report data electronically until EPA has published notice of acceptability in the Federal Register; this may halt or negatively impact current business practices by impeding the ability of the regulated community to conduct its work.
- ◆ If the GLP regulated community will be held to the electronic record-keeping requirements of this Rule, then the analysis of the financial burden to the regulated communities is extremely underestimated.

4. Voluntary "option" of the Proposed Rule:

- ◆ CROMERRR defines an electronic record as "...any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system."
- ◆ The Preamble indicates that "...electronic document submission or electronic record-keeping will be totally voluntary; EPA will not require the submission of electronic documents or maintenance of electronic records in lieu of paper documents or records."
- ◆ By this definition, an electronic record is not only data collected online, but also includes any analysis, distribution, manipulation, tabulation, and storage. Therefore, any company submitting data and reports to EPA would fall under this rule as a result of keeping current with technology. For years, computers have been used to collect, analyze, and tabulate data.
- ◆ Given that the regulated community maintains electronic records for EPA 40 CFR directed programs, it appears that compliance with CROMERRR is not a voluntary act.

5. Lack of available technology to meet record retention requirements

- ◆ Much of the data generated in support of EPA 40 CFR directed programs are collected by commercial off the shelf, third party instruments. Many of these instruments were designed and built without any capability for long-term storage and retrieval of the data. Companies using these instruments cannot with certainty assure that the data can be recalled in human readable form over the lifetime of the retention schedule for that data.

In conclusion, Dow Corning believes that CROMERRR imposes a significant financial burden on the TSCA/FIFRA regulated chemical industry that was not considered in the cost-benefit analysis. Dow Corning believes that a more accurate analysis of costs is necessary before finalization of the rule. We also contend that CROMERRR is not voluntary, as stated in the proposed rule. Electronic systems can be found throughout the regulated community; therefore, we believe compliance with electronic records requirements will be mandatory for a greater number of records than was the intent of the agency.